

IN THE CLAIMS:

Please cancel claims 3 to 12 without prejudice. Please amend the claims as follows:

1. (Currently Amended) A composition comprising a recombinant polynucleotide that encodes a modified ~~blood-clotting factor~~ Factor VII or Factor IX, wherein the modification comprises a proteolytic cleavage site having the sequence Arg Lys Arg Arg-Lys-Arg (SEQ ID NO:1) not normally present in ~~the factor~~ Factor VII or Factor IX, and wherein ~~the factor~~ Factor VII or Factor IX is cleaved at the cleavage site when expressed in an animal cell.
2. (Currently Amended) The composition of claim 1, wherein the ~~blood-clotting factor~~ Factor VII or Factor IX is a functional variant or a functional subsequence of a naturally occurring ~~blood-clotting factor~~ Factor VII or Factor IX.
- 3.-12. (Cancel)
13. (Currently Amended) The composition of claim ~~[[4]]~~ 1, wherein the proteolytic cleavage site is introduced between amino acids 152 and 153 of Factor VII.
14. (Currently Amended) The composition of claim ~~[[4]]~~ 1, wherein the proteolytic cleavage site is introduced between arginine 152 and isoleucine 153 of Factor VII.
15. (Original) The composition of claim 1, wherein the animal cell is mammalian.
16. (Original) The composition of claim 15, wherein the mammalian cell is human.
17. (Currently Amended) The composition of claim 2, wherein the functional variant has one or more conservative amino acid substitutions of wild type ~~blood-clotting factor~~ Factor VII or Factor IX.
18. (Original) The composition of claim 2, wherein the functional variant comprises a Factor VII having increased activity relative to wild type Factor VII.
19. (Original) The composition of claim 2, wherein the functional variant comprises a Factor VII having increased stability *in vivo* relative to wild type Factor VII.

20. (Original) The composition of claim 2, wherein the functional variant comprises a Factor VII having decreased immunogenicity relative to wild type Factor VII.
21. (Currently Amended) The composition of claim 1, wherein the ~~Factor~~ Factor VII or Factor IX is mammalian.
22. (Currently Amended) The composition of claim 21, wherein the ~~Factor~~ Factor VII or Factor IX is primate, canine, feline, porcine, equine or bovine.
23. (Original) The composition of claim 22, wherein the primate is human.
24. (Currently Amended) The composition of claim 1, wherein the recombinant polynucleotide encoding the modified ~~blood clotting factor~~ Factor VII or Factor IX is operatively linked to a regulatable or tissue specific expression control element.
25. (Original) The composition of claim 24, wherein the regulatable or tissue specific expression control element comprises a promoter.
26. (Original) The composition of claim 24, wherein the promoter comprises a skeletal muscle actin promoter or a muscle creatine kinase promoter.
27. (Original) The composition of claim 24, wherein the tissue specific expression control element confers expression of the modified blood clotting factor in muscle, liver, kidney or blood vessel endothelium.
28. (Original) The composition of claim 24, wherein the regulatable expression control element comprises elongation factor 1 α promoter.
29. (Original) The composition of claim 1, further comprising a vector.
30. (Original) The composition of claim 29, wherein the vector comprises a vector suitable for introduction into a cell *in vivo*.

31. (Original) The composition of claim 30, wherein the vector comprises an adeno associated virus (AAV), adenovirus, retrovirus, parvovirus, papilloma virus, reovirus, rotavirus or a herpes virus.
32. (Original) The composition of claim 30, wherein the vector comprises a plasmid vector.
33. (Withdrawn) A polypeptide encoded by the recombinant polynucleotide of claim 1.
34. (Original) A kit comprising a composition of claim 1 or a polypeptide of claim 33.
35. (Original) A kit comprising a composition of claim 1 further including instructions for expressing the modified blood clotting factor *in vitro*, *ex vivo* or *in vivo*.
36. (Withdrawn) The composition of claims 1 or 33, further comprising a cell.
37. (Withdrawn) The composition of claim 36, wherein the cell is a muscle, liver, kidney or blood vessel cell.
38. (Withdrawn) The composition of claim 36, wherein the cell is present in a subject.
39. (Withdrawn) The composition of claim 38, wherein the subject is a non-human transgenic animal.
40. (Withdrawn) The composition of claim 38, wherein the subject is human.
41. (Original) The composition of claims 1, further comprising a pharmaceutically acceptable carrier.
42. (Withdrawn) A method for treating a bleeding or clotting disorder of a subject having or at risk of having a bleeding or clotting disorder comprising administering to the subject an amount of the composition of claim 1 sufficient to ameliorate one or more symptoms of the disorder.
43. (Withdrawn) The method of claim 42, wherein the disorder is amenable to treatment with Factor VII, Factor VIII or Factor IX.

44. (Withdrawn) The method of claim 42, wherein the disorder is caused by insufficient activity or expression of a vitamin-K dependent procoagulant.
45. (Withdrawn) The method of claim 42, wherein the disorder is caused by insufficient platelet aggregation.
46. (Withdrawn) The method of claim 42, wherein the disorder comprises hemophilia or Factor VII deficiency.
47. (Withdrawn) The method of claim 46, wherein the hemophilia comprises hemophilia A or hemophilia B.
48. (Withdrawn) The method of claim 42, wherein the disorder comprises Glanzmann's thrombasthenia.
49. (Withdrawn) The method of claim 42, wherein the disorder comprises Bernard Soulier's thrombasthenia.
50. (Withdrawn) The method of claim 42, wherein the subject produces inhibitory antibodies that bind to a clotting factor.
51. (Withdrawn) The method of claim 50, wherein the inhibitory antibodies bind Factor VIII or Factor IX.
52. (Withdrawn) The method of claim 42, wherein the subject is a mammal.
53. (Withdrawn) The method of claim 42, wherein the mammal is human.
54. (Withdrawn) The method of claim 42, wherein the composition is administered by injection or infusion.
55. (Withdrawn) The method of claim 42, wherein the composition is administered into the portal vein or spleen.

56. (Withdrawn) A method of decreasing clotting time in a subject in need of decreased clotting time comprising administering to the subject an amount of the composition of claim 1 sufficient to decrease clotting time in the subject.
57. (Withdrawn) The method of claim 56, wherein the modified blood clotting factor comprises Factor VII, Factor VIII or Factor IX.
58. (Withdrawn) The method of claim 56, wherein the subject is a mammal.
59. (Withdrawn) The method of claim 58, wherein the mammal is human.
60. (Withdrawn) A method of reducing the frequency or severity of bleeding in a subject in need of reduced frequency or severity of bleeding comprising administering to the subject an amount of the composition of claim 1 sufficient to reduce the incidence or severity of a bleeding in the subject.
61. (Withdrawn) The method of claim 60, wherein the composition comprises Factor VII, Factor VIII or Factor IX.
62. (Withdrawn) The method of claim 60, wherein the subject is a mammal.
63. (Withdrawn) The method of claim 62, wherein the mammal is a human.